

### **REMARKS**

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have amended claims 36, 39, 42, and 45 to specify as refluxing step and submit the claims now present in the application are fully supported by the specification as originally filed (see page 14, lines 23-25). Also, claims have been amended to specify that the ethanol percolates through the elastomer as also fully supported by the specification at page 14, line 25. No new matter is introduced.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

The rejection of claims 36, 37, 42 and 43 under 35 USC 102(b) as being anticipated over DeCrosta et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and further in view of the following comments. Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The DeCrosta reference (US 5550211) relates to the use of supercritical fluids. In contrast, the present invention does not rely on supercritical fluids but instead uses refluxing with a refluxing aliphatic alcohol solvent. The manner in which the refluxing solvent is applied and operates is described on page 14, lines 22 to 31 of the present

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specification. This is plainly different from the supercritical fluid extraction described in DeCrosta as would be appreciated by one of ordinary skill in the art. Refluxing is a claim limitation which cannot be ignore. It is further noted that DeCrosta is primarily concerned with nitrile rubber and supercritical carbon dioxide. Reflux is referred to in passing as an unacceptable procedure which deals primarily with the outer surface of the article as noted in the paragraph bridging columns 1 and 2 of the patent. The notation in the reference with respect to solvents would be understood, in reading the context of the reference to deal with supercritical conditions as noted at column 4 of the reference. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 39, 40, 45 and 46 under 35 USC 103(a) as being unpatentable over DeCrosta in view of Thomas has been carefully considered but is most respectfully traversed in view of the above comments as applied to DeCrosta and further in view of the following comments.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an

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independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

The Thomas reference (US 6234362) refers to EPDM (terpolymer of ethylene, propylene and a diene) seal materials. This is in contrast to the amended claims, which relate to an isobutylene polymer or co-polymer thereof selected from one or more of polyisobutylene, polybutene, butyl rubber and halogenated butyl rubber. More importantly, Thomas is silent regarding the problem of extractables and leachables in seal materials for pharmaceutical use and there is no teaching of refluxing in accordance with the presently claimed invention. Certainly Thomas provides no teaching or suggestion to carry out a solvent extraction let alone a solvent extraction using a refluxing aliphatic alcohol by refluxing. A combination of DeCrosta and Thomas also does not lead to the present claimed invention. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 38 and 44 under 35 USC 103(a) as being unpatentable over DeCrosta in view of Adeji or Cripps has been carefully considered but is most respectfully traversed in view of the above comments as applied to DeCrosta. The further teaching of the secondary reference does not overcome the deficiencies of the primary reference. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 41 and 47 under 35 USC 103(a) as being unpatentable over DeCrosta in view of Thomas as applied to claims 39 and 45 above and further in view of Adeji or Cripps has been carefully considered but is most respectfully traversed in view of the above comments as applied to DeCrosta and Thomas and further in view of the following comments.

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Applicants submit that the Cripps and Adjei references are clearly less relevant than the DeCrosta and Thomas references and do not overcome the deficiencies of the primary reference for the reasons discussed above. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,  
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